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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	Q115525	7156

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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
08/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/535,341	JUNG ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-7,13 and 15*.
   Claim(s) withdrawn from consideration: *8-12*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Chun Dahle/
Examiner, Art Unit 1644

Continuation of 5. Applicant's reply has overcome the following rejection(s): provisional double patenting rejections against copending USSNs 10/535,231 and 10/535,232.

Continuation of 11. does NOT place the application in condition for allowance because:

1. Applicant's submission, of computer readable form of the sequence listing and paper copy thereof, and the statement that the content of the paper and computer readable copies are the same, filed on July 27, 2010, is entered.

2. In view of timely filed terminal disclaimers in compliance with 37 CFR 1.321(c) or 1.321(d), the prior provisional obviousness type double patenting rejection against USSNs 10/535,231 and 10/535,232 have been withdrawn.

3. Claims 1-7, 13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by Kostenuik et al. (US Patent 6,756,480, reference of record) for reasons of record.

Applicant's arguments, filed on July 27, 2010, have been fully considered but have not been found persuasive.

Applicant argues that column 3 of the Kostenuik et al. discloses linking Fc domain of an antibody to polymers and incorporate by reference to USSN 09/428,082, PCT appl. No. WO 99/25044. Applicant then asserts that US Patent 6,660,843 which corresponds to PCT publication no. 99/25044, wherein the '843 Patent was incorporated by the prior art of record (Kostenuik et al.) discloses details of the Fc fusion technique by expressin polypeptide and Fc fragment coincidentally using one expression vector in one expression cell. Therefore, applicant concludes that Kostenuik et al. fails to teach a Fc fragment as carrier and fails to enable the make of a Fc fragment carrier. Applicant repeats that the prior art teach a non-peptide linker used together with additional vehicle such as a polymer and a peptide linker used together with a peptide vehicle with is in the Fc domain. As such, applicant asserts that the instant claims, drawn to an Fc fragment as a drug carrier wherein the Fc fragment is covalently linked to a drug through a non-peptide linker, are not anticipated by Kostenuik et al.

This is not found persuasive for following reasons:

Contrary to applicant's reliance on BACKGRAOUND OF THE INVENTION on column 3 of Kostenuik et al., it is noted that a prior art reference must be considered in its entirety, see MPEP 2141.02. Here, applicant appears to ignore the clear teachings of Kostenuik et al. regarding attaching Fc domain to polypeptide covalently via a linker, wherein the linker is PEG (e.g. see claims 1 and 2 and definition of linkers on columns 33-34). Further, in response to applicant's argument that the prior art does not teach an Fc as a drug carrier, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Here, although the prior art does not explicitly teach an Fc as a drug carrier, the prior art structure of the Fc linked to polypeptide via linkers such as PEG is capable of performing the intended use as a drug carrier. Therefore, the reference teachings meet the claimed limitation.

Furthermore, contrary to applicant's assertion that the prior art is not enabled, the courts have ruled that enablement and art are distinct issues, stating in Rasmusson v. SmithKlein Beecham Corp., 75 USPQ2d 1297 (CAFC 2005), that:
"The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In In re Hafner, 410 F.2d 1403 161 USPQ 783 (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." Id. at 1405; see Schoenwald, 964 F.2d at 1124; In re Samour, 571 F.2d 559, 563-64 197 USPQ 1 (CCPA 1978). The reason is that section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." Hafner, 410 F.2d at 1405; see 1 Donald S. Chisum, Chisum on Patents §3.04[1][c] (2002); see also In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349-52 64 USPQ2d 1202 (Fed. Cir. 2001) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method)."

As stated previously, the teachings of Kostenuik et al., when considered in its entirety, would encompass a prathyroid hormone peptide (PHP) covalently linked to an Fc region (e.g. IgG4 Fc region) via non-peptide linker including PEG (e.g. see linkers defined on columns 33-34). Specifically, Kostenuik et al. claims

"1. A polypeptide comprising a parathyroid hormone (PTH) peptide and a Fc domain, wherein said Fc domain is covalently attached to the C-terminus of said
PTH peptide.

2. The polypeptide of claim 1 further comprising a linker attaching said Fc domain to said PTH peptide."

On columns 33-34, Kostenuik et al. define that a linker can be PEG.

Therefore, the prior art's polypeptide comprising a PTH and a Fc domain wherein said Fc domain is covalently attached to the

PTH via a linker including PEG would meet the claimed limitation of an Fc fragment covalently linked to a drug through a non-peptide linker including PEG.

Therefore, applicant's arguments have not been found persuasive.

4. Claims 1-7, 13, and 15 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 24 of copending USSN 11/747,153 and claims 1-25 of copending USSN 11/910,962 and claims 1-26 and 33 of copending USSN 11/947,697 for reasons of record.
This is a provisional obviousness-type double patenting rejection because the
conflicting claims have not in fact been patented.
Applicant requests to hold the rejection abeyance.
Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

5. Applicant's statement that the copending USSNs 11/747,153, 11/910,962, and 11/947,697 and the instant application were commonly owned at the time the instant invention was made is acknowledged.